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-- REMARKS --

The present amendment replies to a Final Office Action dated August 27, 2003 and an Advisory Action dated December 4, 2003. Claims 1-27 are currently pending in the present application.

In the Final Office Action, the Examiner rejected pending claims 1-27 on various grounds. The Applicants respond to each ground of rejection as subsequently recited herein, and respectfully request reconsideration and further examination of the present application:

- A. Claims 1-3, 6, 8-10, 12, 14, 16, and 27 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,066,156 to Yan.

The Applicant traverses the 35 U.S.C. §102(b) rejection of independent claims 1, 9, 22, and 27 because *Yan* fails to disclose, teach, or suggest each and every element of the balloon, balloon stent assemblies, and method of retaining a stent on a balloon of the present invention. Applicant further traverses the rejections of dependent claims 2, 3, 6, 8, 10, 12, 14, and 16. Specifically, *Yan* fails to disclose, teach, or suggest the limitation of flowing a balloon outer layer portion into stent gaps when said portion is heated to a predetermined temperature, wherein the "outer layer portion flows into gaps formed in the stent" as claimed in claims 1 and 9. Further, *Yan* fails to disclose, teach or suggest "an outer layer means for flowing into gaps" as claimed in claim 27.

Yan discloses a stent delivery catheter comprising a catheter body having a deflated balloon portion, a layer of heat sensitive adhesive disposed on the balloon portion, wherein the adhesive is tacky at or below a temperature T, and is non-tacky at above T; and wherein the stent is disposed on the layer of heat sensitive adhesive (see column 2; lines 46-52).

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In one embodiment of *Yan*, interstitial spaces of the stent may be at least partially filled by applying an adhesive (see column 5, lines 3-6). However, *Yan* does not disclose that heating the adhesive is necessary or even preferable for its application. As such, *Yan* does not disclose, teach, or suggest that heating of the adhesive would result in or is coupled with flowing of the adhesive into stent gaps.

In other embodiments, *Yan* discloses that adhesive may in fact be heated, but that the heating is used to accomplish the following: A) making the adhesive non-tacky to release the stent during deployment (see column 3, line 65 through column 4, line 2); B) making the adhesive non-tacky to allow the stent to facilitate stent mounting onto the balloon (see column 6, lines 51-58); or C) making the adhesive tacky for an undisclosed reason (see column 7, lines 31-34).

In embodiment A), the adhesive is heated to a predetermined temperature within the blood vessel resulting in a phase change during stent deployment (e.g., a tacky to a non-tacky state). This embodiment reaches away from a strategy of heating to cause adhesive flow into stent gaps. For example, heating is not used to retain the stent to the balloon; rather, the stent is released from the balloon as the adhesive is heated. In fact, the predetermined temperature described by *Yan* is preferably in the range of 38-47 degrees Celsius (see column 3, lines 52-54), a temperature corresponding to *in-vivo* conditions and suited for *in-vivo* stent deployment, and not generally optimal for flowing adhesive into stent gaps.

In embodiment B), the adhesive may be heated to make it non-tacky to facilitate stent mounting. Although heating may be used during or prior the stent mounting, this embodiment does not disclose that the heating is associated with any adhesive flow into stent gaps. In fact, this embodiment reaches away from heating to cause adhesive flow into stent gaps. The mounting process described by *Yan* allows

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"easy" alignment and adjustment of the stent after the adhesive has been heated (see column 6, lines 49-58), a process not "easily" achievable when flowing adhesive into stent gaps.

In embodiment C), a provision is made for the adhesive to alternatively become tacky once heated, however a specific application of this alternative is not discussed. Because adhesive tackiness properties are not necessarily associated with adhesive flow properties, heating the adhesive to make it tacky does not necessarily suggest that adhesive flow will result (e.g., as a function of adhesive viscosity). As such, *Yan* embodiment C) does not disclose that heating is associated with adhesive flow into stent gaps.

In contrast to *Yan*, independent claims 1 and 9 and independent claims 22 and 27 as amended of the present application each include the limitation of flowing an outer layer portion 22 into stent gaps 33 when heated to a predetermined temperature. As discussed above, this limitation is not disclosed, taught, or suggested, in the *Yan Patent*. Independent claims 1, 9 and 27 cannot be anticipated by *Yan* under 35 U.S.C. §102(b). Accordingly, allowance of independent claims 1, 9 and 27 is respectfully requested.

Regarding claims 2, 3, 6, 8, 10, 12, 14, and 16, said claims depend from independent claims 1 and 9. Therefore, dependent claims 2, 3, 6, 8, 10, 12, 14, and 16 include all of the elements and limitations of independent claims 1 and 9. It is therefore respectfully submitted by the Applicant that dependent claims 2, 3, 6, 8, 10, 12, 14, and 16 are allowable over *Yan* for at least the same reasons as set forth above with respect to independent claims 1 and 9.

Therefore, for the reasons mentioned above, withdrawal of the Rejection under 35 U.S.C. § 102(b) for claims 1-3, 6, 8-10, 12, 14, 16, and 27 is respectfully requested.

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B. Claims 1-3, 5, 9, 10, 12, 14, 16, 18, and 22-27 were rejected under 35 U.S.C. §102(b) as being anticipated by W/O 95/33422 to Stoltze.

The rejection of claims 1-3, 5, 9, 10, 12, 14, 16, 18, 22-27 under 102(b) as anticipated by *Stoltze* is traversed. Specifically, *Stoltze* fails to disclose, teach, or suggest the limitation of flowing a balloon outer layer portion into stent gaps when said portion is heated to a predetermined temperature, wherein the "outer layer portion flows into gaps formed in the stent" as claimed in claims 1 and 9. Further, *Stoltze* fails to disclose, teach or suggest "an outer layer means for flowing into gaps" as claimed in claim 27.

At most, *Stoltze* discloses that a catheter is heated, prior to depressing a stent into the surface of the catheter. See page 14, line 14 to page 15 line 5. This disclosure simply cannot anticipate the invention claimed in claims 1, 9, 22 and 27, wherein an "outer layer portion flows into gaps formed in the stent" as claimed in claims 1 and 9. Further, *Stoltze* fails to disclose, teach or suggest "flowing an outer layer of the balloon into the gaps" as claimed in claim 22 and "an outer layer means for flowing into gaps" as claimed in claim 27.

Additionally, *Stoltze* discloses neither an inner layer, nor an inner layer portion that "does not flow into the gaps" as claimed in claim 1, nor an outer layer "disposed on a limited area of an inner layer" as further claimed in claim 1, nor an "inner layer does not flow" as claimed in claim 9, nor a method including a step wherein "an inner layer of the balloon does not flow" as claimed in claim 22, nor inner layer means "wherein the inner layer means does not flow into the gaps when at the predetermined temperature" as claimed in claim 27.

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Claims 2-3, and 5 depend directly or indirectly from claim 1 and are therefore allowable over *Stoltze* for at least the same reasons. Claims 10, 12, 14, 16 and 18 depend directly or indirectly from claim 9 and are therefore allowable over *Stoltze* for at least the same reasons. Claims 23-26 depend directly or indirectly from claim 22 and are therefore allowable over *Stoltze* for at least the same reasons.

At a very minimum, *Stoltze* does not disclose that the outer layer and inner layer is a co-extruded laminate, as claimed in claim 3, and therefore, at least claim 3 is patentable over *Stoltze*. Applicant notes that claim 17 claims similar subject matter as claim 3, but claim 17 was not rejected under *Stoltze*. Likewise, *Stoltze* does not disclose, teach, or suggest that the outer layer may be a tie layer material, as claimed in claims 5 and 18, and therefore at least claims 5 and 18 are patentable over *Stoltze*.

Withdrawal of the rejections to claims 1-3, 5, 9, 10, 12, 14, 16, 18, 22-27 is requested.

C. Claims 1-21 and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,807,327 to Green et al. in view of U.S. Patent No. 6,066,156 to Yan.

Applicant traverses the 35 U.S.C. §103(a) rejection of claims 1-21 and 27 herein because *Green* and *Yan* fail to disclose, teach, or suggest each and every element, alone or in combination, of the balloon stent assemblies of the present invention.

To make a *prima facie* case of obviousness under § 103(a), all of the *claimed* elements of the invention must be taught or suggested by the prior art (MPEP § 2143.03). When evaluating claims for obviousness under § 103(a), all the limitations of the claims must be considered and given weight. Regarding independent claims 1 and 9, neither *Green* nor *Yan* disclose, teach, or suggest flowing the outer layer portion 22 into stent gaps 33 when heated to a predetermined temperature.

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The Examiner states that "Green does not disclose that the outer layer portion flows into gaps..." The Applicant agrees, and maintains, as discussed above, that the *Yan Patent* does not disclose, teach, or suggest flowing the outer layer portion 22 into stent gaps 33 when heated to a predetermined temperature. As this limitation is not disclosed, taught, or suggested, the cited references cannot be used to render unpatentable independent claims 1 and 9 under § 103(a).

There is no suggestion in *Green* in view of *Yan* to modify in this fashion, and there is no motivation provided and supported by evidence. In order to prove a prima facie case of obviousness, the Examiner is required to provide affirmative evidence to support such a position. The motivation to modify or combine must come from the references themselves. See MPEP 2143.01. A conclusory allegation that "[I]t would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of *Green* with the adhesive taught in *Yan* in order to prevent stent movement or detachment, prevent adhesive residue from being left on the stent after deployment and to form a smoother profile to be inserted into a vessel." entirely fails to meet the Examiner's evidentiary burden to prove a prima facie case. The motivation to combine or modify cannot come from the Examiner, without the taking of official notice, or preparation of an Examiner's affidavit. Without some evidence of a motivation to combine, this rejection cannot stand.

Furthermore, the mere fact that the references could be combined to arrive at the claimed invention (which Applicant does not concede) is insufficient to prove a prima facie case. See MPEP 2143.01, *In Re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) and *In Re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). While applicants do not agree that the combination of the references would result in the claimed invention, there must be some motivation or suggestion in the references to combine to support a prima facie case of obviousness. In the absence of any such motivation or suggestion, the rejection must fail.

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Additionally, as described in the Graham case, the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention. *See Graham v. John Deere Co.*, 383 U.S. 1 (1965). In this case, the Examiner appears to have engaged in impermissible hindsight, as there is a void of evidence around the Examiner's allegation of obviousness. In view of the fact that the Examiner was entirely unable to support the allegation of obviousness with a citation to a suggestion or motivation within the references themselves to either *Green* or *Yan*, the Examiner's use of impermissible hindsight is apparent.

Withdrawal of the rejections to claims 1, 9, 22 and 27 is requested

Regarding claims 2-8 and 10-21, said claims depend from independent claims 1 and 9. Therefore, dependent claims 2-8 and 10-21 include all of the elements and limitations of independent claims 1 and 9, respectively. It is therefore respectfully submitted by the Applicant that dependent claims 2-8 and 10-21 are allowable over the *Green* and *Yan* Patents for at least the same reasons as set forth above with respect to independent claims 1 and 9. Allowance of dependent claims 2-8 and 10-21 is respectfully requested. *See* MPEP 2143.03 and *In Re Fine* (where an independent claim is non-obvious, any claims depending therefrom are also nonobvious.)

Therefore, for the reasons mentioned above, withdrawal of the rejection under 35 U.S.C. § 103(a) for claims 1-21 is respectfully requested.

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D. The Advisory Action

The Advisory Action issued December 4, 2003 does not prove a prima facie case and does not serve to overcome Applicant's arguments.

First, contrary to the Examiner's assertion, Yan does not disclose an invention as claimed herein. Although Yan does disclose a "heatable adhesive," as alleged by the Examiner, the instant case does not claim a heatable adhesive. Indeed, the instant case *does not claim an adhesive at all*. While the outer layer may adhere to the stent, the adhesion is attained without the use of adhesives. Likewise, whether "Yan's adhesive could be used in the manner that applicant claims" entirely misconstrues the claims. Applicant does not use an adhesive, and rather adheres the balloon to the stent using the structures and methods specified in the claims.

The Examiner also argues that *Stoltze* discloses an outer layer that is heated to soften the outer layer so that the stent becomes embedded in the balloon. The Examiner has misconstrued *Stoltze* however. *Stoltze* discloses a single layer balloon that is embedded in the stent upon the application of heat and force. See, *inter alia* *Stoltze*, page 13 line 30 – page 14 line 13. *Stoltze* does not disclose an outer layer distinguished from the inner layer. *Stoltze* simply does not disclose an inner layer, or an inner layer portion that "does not flow into the gaps" as claimed in claim 1, or an "inner layer does not flow" as claimed in claim 9, or a method including a step wherein "an inner layer of the balloon does not flow" as claimed in claim 22, or inner layer means "wherein the inner layer means does not flow into the gaps when at the predetermined temperature" as claimed in claim 27. Furthermore, *Stoltze* does not disclose that the outer layer and inner layer is a co-extruded laminate, as claimed in claim 3, and therefore, at least claim 3 is patentable over *Stoltze*. Likewise, *Stoltze* does not disclose, teach, or suggest that the outer layer may be a tie layer material, as claimed in claims 5 and 18, and therefore at least claims 5 and 18 are patentable over *Stoltze*.

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Additionally, the Examiner did not address Applicants response to the 103(a) rejections of *Green* in view of *Yan*, and Applicants believe that this rejection has been obviated by their arguments.

Applicant has amended the claims, not to narrow their scope, but rather to clarify the claimed invention. Claims 1-28 are patentable over the prior art.

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SUMMARY

Examiner Baxter's rejections have been obviated by the amendment to independent claims 1 and 27 and the above remarks. The Applicant respectfully submits that claims 1-27 fully satisfy the requirements of 35 U.S.C. §§ 102, 103 and 112. In view of the foregoing amendments and remarks, favorable consideration and early passage to issue of the present application are respectfully requested.

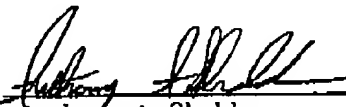
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